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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/634,643	LASHINSKI ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *16,18 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Claim 1 has been amended to add the language of "actuating a control element on the catheter to selectively advance".

Claims 1-15,17,19 are pending for consideration. Claims 16,18,20-23 have been withdrawn from consideration as being directed to an independent invention/species. Claims 24-54 have been cancelled.

Priority

The earliest priority application which claim 1 is fully supported by is provisional application 60/429,281. Therefore, claim 1 has an effective filing date of November 25, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Solem et al. (USPN 6,210,432, as cited in applicant's IDS).

Solem et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1. See column 2, lines 45-46, column 4, lines 6-8 and 16-18, and column 5, lines 12-13 for providing a catheter (introduction sheath) having a prosthesis (8) thereon, inserting the catheter into the venous system and transluminally advancing the prosthesis (8) into the coronary sinus (5). See column 4, lines 21-25 and Figures 2 and 3 for advancing at least one tissue anchor (10) from a retracted position to an extended position. See column 4, lines 29-38 and Figures 5, 6, 8 and 9 for manipulating a component of the prosthesis (8) by releasing it from its stretched/extended state to cause the prosthesis (8) to exert force on the mitral valve annulus (6).

Applicant's amendment, as broadly worded, fails to distinguish over the method of Solem et al. In column 4, Solem et al provides a cover sheet that is selectively retracted thereby exposing the body allowing the hooks to extend into the adjacent tissue. Applicant's added limitation of "actuating a control element on the catheter to selectively advance" does not preclude or distinguish over the action of Solem et al. The device of Solem et al requires some form of control element which is effected to provide the retraction of the cover sheet. Accordingly, once the cover sheet is selectively retracted, this action allows for the extension of the anchor elements from a retracted position to engage the adjacent tissue.

The elongate body **8** is locked onto the stabilizing instrument **12**, as shown in FIG. **5**, and introduced into the long cover sheet **11** of synthetic material. This aggregate is then pushed through the introduction sheet and the venous system to the coronary sinus **5** riding on the guiding wire. After exact positioning of the elongate body **8** in the coronary sinus **5**, as illustrated in FIG. **8** where the mitral valve **19** is shown having central gap **20**, the cover sheet **11** is retracted exposing the elongate body **8** within the coronary sinus **5**. This maneuver allows the hooks **10** on the elongate body **8** to dig into the walls of the coronary sinus **5** and into the heart. The elongate body **8** is still locked on to the stabilizing instrument **12** such that the hooks **10** engage the walls of the coronary sinus **5** in the stretched or extended state of the elongate body **8**.

Claim 2, see column 4, lines 6-8 and 16-18 for percutaneously accessing the venous system prior to the transluminally advancing step.

Claims 7 and 8, see Figures 2 and 3 for the tissue anchor (10) having a proximal end for piercing tissue (column 4, lines 23-25) and a distal point of attachment to the prosthesis (8), wherein the anchor (10) is rotated about the point of attachment from an axial orientation to an inclined orientation.

Claims 9 and 10, see Figures 2 and 3 for advancing at least two tissue anchors (10) to an extended position.

Claim 11, see Figure 9 for the prosthesis (8) transforming into a curved configuration having a first side facing towards the mitral valve annulus (6) and a second side facing away from the mitral valve annulus (6).

Claim 12, see Figures 3 and 9 for advancing at least two tissue anchors (10) in the direction of the mitral valve annulus (6).

Claim 13, see Figure 3 for first and second tissue anchors (10) inclining outwardly from the prosthesis (8) in a distal direction and in a proximal direction, respectively.

With respect to claim 14, see the embodiment shown in Figures 12 and 13. See column 2, lines 45-46 and column 5, lines 12-13 for providing a catheter having a prosthesis (8") thereon, inserting the catheter into the venous system and transluminally advancing the prosthesis into the coronary sinus (5). See column 4, lines 56-62 and Figure 12 for advancing at least one tissue anchor (23, 24, 25) from a retracted position to an extended position. See columns 4-5, lines 62-4 and Figure 13 for axially moving a forming element (26, 27) with respect to the prosthesis (8") to cause the prosthesis (8") to bend and exert force on the mitral valve annulus (6).

8. Claims 1-3, 7, 9, 15 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohn et al. (USPN 6,890,353).

Cohn et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1. See Figure 5 and column 5, lines 46-51 for providing a catheter (109) having a prosthesis (106) thereon, inserting the catheter (109) into the venous system, and transluminally advancing the prosthesis (106) into the coronary sinus (30). See Figures 6-8 for advancing at least one tissue anchor (139, 142) from a retracted position to an extending position. See Figure 9 and column 7, lines 41-48 for manipulating a component (124) of the prosthesis (106) to cause the prosthesis (106) to exert a force on the mitral valve annulus.

Claims 2 and 3, see column 5, lines 46-51 and column 6 lines 63-67 for percutaneously accessing the jugular vein (18) prior to the transluminally advancing step.

Claim 7, see Figures 6 and 8 for advancing at least one tissue anchor (142) from an axial orientation to an inclined orientation.

Claim 9, see Figures 6 and 8 for advancing at least two tissue anchors (139, 142) to an extended position.

Claims 15 and 17, see Figures 3 and 9, column 6, lines 45-49, column 7, lines 41-48 and column 8, line 3 for locking the prosthesis (106) by providing an interference fit (ratcheting) to retain a force on the annulus following the manipulating step.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Rhee et al. (USPN 6,019,739, as cited in applicant's IDS).

Solem et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1, but are silent to the additional steps of measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the inserting step, as required by claim 4. The examiner contends that measuring a body part for

selecting an appropriately sized prosthesis is old and well known in the art. For example, Rhee et al. teach measuring the size of a heart valve annulus during annuloplasty surgery in order to select a properly sized annuloplasty ring. See column 1, lines 5-11. Therefore, it would have been obvious to one of ordinary skill in the art to measure the coronary sinus and then select an appropriately size prosthesis prior to the inserting step in order for the prosthesis to function properly, without being displaced for being too small or damaging tissue for being too big for examples, once it is inserted into the coronary sinus.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Rhee et al.

Cohn et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1, but are silent to the additional steps of measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the inserting step, as required by claim 4. The examiner contends that measuring a body part for selecting an appropriately sized prosthesis is old and well known in the art. For example, Rhee et al. teach measuring the size of a heart valve annulus during annuloplasty surgery in order to select a properly sized annuloplasty ring. See column 1, lines 5-11. Therefore, it would have been obvious to one of ordinary skill in the art to measure the coronary sinus and then select an appropriately size prosthesis prior to the inserting step in order for the prosthesis to function properly, without being displaced for being too small or damaging tissue for being too big for examples, once it is inserted into the coronary sinus.

12. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Griffith et al. (USPN 5,390,661, as cited in applicant's IDS).

Solem et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1, but are silent to the additional step of measuring the hemodynamic function using transesophageal echo cardiography, as required by claims 5 and 19. Griffith et al. teach that it is old and well known in the art to monitor hemodynamic function using transesophageal echocardiography to assess mitral regurgitation during mitral valve repair. See column 1, lines 7-8 and 24-28. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Griffith et al. to include to the method of Solem et al. the step of monitoring hemodynamic function using transesophageal echo cardiography to assess mitral valve regurgitation because it is old and well known in the art to do so. Examiner contends the monitoring will determine if sufficient repair has been done or if further repair is needed.

13. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Griffith et al.

Cohn et al. disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 1, but are silent to the additional step of measuring the hemodynamic function using transesophageal echo cardiography, as required by claims 5 and 19. Griffith et al. teach that it is old and well known in the art to monitor

hemodynamic function using transesophageal echocardiography to assess mitral regurgitation during mitral valve repair. See column 1, lines 7-8 and 24-28. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Griffith et al. to include to the method of Cohn et al. the step of monitoring hemodynamic function using transesophageal echo cardiography to assess mitral valve regurgitation because it is old and well known in the art to do so. Examiner contends the monitoring will determine if sufficient repair has been done or if further repair is needed.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Griffith et al. as applied to claim 5 above, and further in view of Kadhiresan (USPN 5,935,081, as cited in applicant's IDS).

Solem et al., as modified by Griffith et al., disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 5, but are silent to the additional step of determining an ongoing drug therapy taking into account post implantation hemodynamic function, as required by claim 6. Kadhiresan teaches monitoring the heart beat of a patient suffering from cardiac abnormalities, and in the presence of a third heart sound, which indicates mitral regurgitation, optimizing a drug therapy for treatment thereof. See column 4, lines 8-46. Therefore, it would have been obvious to one of ordinary skill in the art to look to the teachings of Kadhiresan to add to the method of Solem et al. and Griffith et al. the step of determining an optimized

ongoing drug therapy taking into account post implantation hemodynamic function, including residual regurgitation.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Griffith et al. as applied to claim 5 above, and further in view of Kadhiresan.

Cohn et al., as modified by Griffith et al., disclose a method of performing transluminal mitral annuloplasty with all the elements of claim 5, but are silent to the additional step of determining an ongoing drug therapy taking into account post implantation hemodynamic function, as required by claim 6. Kadhiresan teaches monitoring the heart beat of a patient suffering from cardiac abnormalities, and in the presence of a third heart sound, which indicates mitral regurgitation, optimizing a drug therapy for treatment thereof. See column 4, lines 8-46. Therefore, it would have been obvious to one of ordinary skill in the art to look to the teachings of Kadhiresan to add to the method of Cohn et al. and Griffith et al. the step of determining an optimized ongoing drug therapy taking into account post implantation hemodynamic function, including residual regurgitation.

Response to Arguments

Applicant's arguments filed 6/23/2006 have been fully considered but they are not persuasive. As explained in the body of the rejection, applicant's amendment, as broadly worded, fails to distinguish over the method of Solem et al. In column 4, Solem

et al provides a cover sheet that is selectively retracted thereby exposing the body allowing the hooks to extend into the adjacent tissue. Applicant's added limitation of "actuating a control element on the catheter to selectively advance" does not preclude or distinguish over the action of Solem et al. The device of Solem et al requires some form of control element which is effected to provide the retraction of the cover sheet. Accordingly, once the cover sheet is selectively retracted, this action allows for the extension of the anchor elements from a retracted position to engage the adjacent tissue

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
11/23/2006